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119 F.3d 1559
119 F.3d 1559, 43 U.S.P.Q.2d 1398
(Cite as: 119 F.3d 1559)

Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.

The REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiff-Appellant,
v.
ELI LILLY AND COMPANY, Defendant-Appellee.

No. 96-1175.

July 22, 1997.
Rehearing Denied; Suggestion for Rehearing In Banc Declined Oct. 24, 1997.

Regents of university which held patents relating to recombinant DNA technology brought infringement action against manufacturer of human insulin. The United States District Court for the Southern District of Indiana, S. Hugh Dillin, J., entered judgment for manufacturer on grounds that manufacturer did not infringe patents, that asserted claims of one patent were invalid, and that both patents were unenforceable. Regents appealed. The Court of Appeals, Lourie, Circuit Judge, held that: (1) transfer of action to district which directed pretrial proceedings was not barred by Eleventh Amendment; (2) transfer of venue was not abuse of discretion; (3) first patent was invalid for failure to comply with statutory written description requirement; (4) patent applicant did not engage in inequitable conduct by misrepresenting type of plasmid used in examples of patent application; (5) first patent was not unenforceable under doctrine of unclean hands; (6) manufacturer did not infringe second patent; and (7) patent applicant did not engage in inequitable conduct by failing to disclose reference that was cumulative.

Affirmed in part and reversed in part.

West Headnotes

[1] **Federal Courts** 265
170Bk265 Most Cited Cases

Transfer of state university's patent infringement claim against manufacturer of human insulin to district court in another state did not violate Eleventh Amendment, as state itself asserted claim and did not have any claims asserted against it. U.S.C.A. Const.Amend. 11.

[2] **Federal Courts** 110
170Bk110 Most Cited Cases

District court in Indiana, which conducted pretrial proceedings in consolidated cases relating to recombinant DNA technology, did not abuse its discretion by transferring venue for trial on merits, in patent infringement case, from district court in California to itself, even though Indiana court emphasized judicial economy over other factors, which court found did not favor either party. 28 U.S.C.A. § 1404(a).

[3] **Federal Courts** 101
170Bk101 Most Cited Cases

Consideration of interest of justice, which includes judicial economy, may be determinative to particular motion to transfer venue, even if convenience of parties and witnesses might call for different result. 28 U.S.C.A. § 1404(a).

[4] **Federal Courts** 915
170Bk915 Most Cited Cases

Patent infringement plaintiff waived claim that transfer of its action by district court which conducted pretrial proceedings in consolidated cases, for trial on merits before that court, was barred by statute, where plaintiff failed to raise claim in opening brief on appeal from final judgment, notwithstanding fact that plaintiff asserted claim in petition for mandamus seeking to vacate transfer order for consolidation of discovery. 28 U.S.C.A. § 1407(a); F.R.A.P.Rule 28(a)(6), (c), 28 U.S.C.A.

[5] **Patents** 314(5)
291k314(5) Most Cited Cases

[5] **Patents** 324.5
291k324.5 Most Cited Cases

Whether patent specification complies with statutory written description requirement is question of fact,

which Court of Appeals reviews for clear error on appeal from bench trial. 35 U.S.C.A. § 112.

[6] Patents 99
291k99 Most Cited Cases

To fulfill statutory written description requirement, patent specification must describe invention and do so in sufficient detail that one skilled in the art can clearly conclude that inventor invented claimed invention. 35 U.S.C.A. § 112.

[7] Patents 98
291k98 Most Cited Cases

Patent applicant complies with statutory written description requirement by describing invention, with all its claimed limitations, not that which makes it obvious, and by using such descriptive means as words, structures, figures, diagrams, and formulas that set forth claimed invention. 35 U.S.C.A. § 112.

[8] Patents 98
291k98 Most Cited Cases

Adequate written description of DNA that is subject of patent requires precise definition, such as by structure, formula, chemical name, or physical properties, not mere wish or plan for obtaining claimed chemical invention, and, thus, adequate written description of a DNA requires more than mere statement that it is part of invention and reference to potential method for isolating it but requires description of DNA itself.

[9] Patents 99
291k99 Most Cited Cases

Claim of patent directed to recombinant procaryotic microorganism modified to encode human insulin was invalid, because patent specification did not fulfill statutory written description requirement; although specification provided adequate written description of rat cDNA, it provided only general method of producing human insulin cDNA, not written description of human insulin cDNA, as required by asserted claim. 35 U.S.C.A. § 112.

[10] Patents 98
291k98 Most Cited Cases

Claims of patent relating to recombinant DNA technology which generically recited cDNA encoding vertebrate insulin, claim which was directed generically to cDNA encoding mammalian insulin, and dependent claims which recited cDNA encoding vertebrate insulin did not adequately describe claimed invention for plasmid and microorganism that produced human insulin, notwithstanding disclosure of particular species within scope of those generic claims. 35 U.S.C.A. § 112.

[11] Patents 99
291k99 Most Cited Cases

Patent specification's written description of invention involving chemical genus, like description of chemical species, requires precise definition, such as by structure, formula, or chemical name, of claimed subject matter sufficient to distinguish it from other materials. 35 U.S.C.A. § 112.

[12] Patents 98
291k98 Most Cited Cases

Description requirement of patent statute requires description of invention, not indication of result that one might achieve if one made that invention. 35 U.S.C.A. § 112.

[13] Patents 98
291k98 Most Cited Cases

Description of genus of cDNAs referred to in patent may be achieved by means of recitation of representative number of cDNAs, defined by nucleotide sequence, falling within scope of genus or of recitation of structural features common to members of genus, which features constitute substantial portion of genus. 35 U.S.C.A. § 112.

[14] Patents 97
291k97 Most Cited Cases

District court abused its discretion in finding that applicant for patent relating to recombinant DNA technology engaged in inequitable conduct before Patent and Trademark Office (PTO) by violating National Institutes of Health (NIH) guidelines on use of plasmids and misrepresenting type of plasmid used in examples of patent application, absent evidence that noncompliance with guidelines or distinction between plasmid named in examples and plasmid actually used would have been considered material by reasonable patent examiner.

[15] Patents 97
291k97 Most Cited Cases

Determination of inequitable conduct in obtaining patent is committed to district court's discretion, and Court of Appeals thus reviews district court's judgment for abuse of discretion.

[16] Patents 324.54
291k324.54 Most Cited Cases

To overturn discretionary ruling of district court regarding inequitable conduct in applying for patent, appellant must establish that ruling is based on clearly erroneous findings of fact or on misapplication or misinterpretation of applicable law, or evidences clear error of judgment on part of district court.

[17] Patents 97
291k97 Most Cited Cases

Alleged patent infringer asserting inequitable conduct defense must demonstrate by clear and convincing evidence that applicant or applicant's attorney either failed to disclose material information or submitted false material information to Patent and Trademark Office (PTO) and that applicant or attorney did so with an intent to deceive PTO; information is material if reasonable examiner would have considered it important to patentability of claim.

[18] Patents 97
291k97 Most Cited Cases

Patent relating to recombinant DNA technology was not unenforceable under doctrine of "unclean hands," based on applicant's alleged misrepresentation of type of plasmid used in examples of patent application, absent proof that misrepresentation was material.

[19] Patents 250
291k250 Most Cited Cases

[19] Patents 251
291k251 Most Cited Cases

Manufacturer of human insulin which used semi-synthetic DNA to yield cleavable fusion protein did not infringe, either literally or under doctrine of equivalents, patent for invention which directly expressed human proinsulin (PI); patentee surrendered coverage of constructs which expressed recombinant fusion protein to overcome prior art rejections.

[20] Patents 226.6
291k226.6 Most Cited Cases

In determining whether patent has been infringed, claim must first be properly construed to determine its scope and meaning, and, second, claim as properly construed must be compared to accused device or process.

[21] Patents 314(5)
291k314(5) Most Cited Cases

[21] Patents 324.5
291k324.5 Most Cited Cases

Claim construction, in patent infringement action, is question of law which Court of Appeals reviews de novo; proper construction of claims is based upon claim language, specification, prosecution history, and, if necessary to aid court's understanding of patent, extrinsic evidence.

[22] Patents 314(5)
291k314(5) Most Cited Cases

[22] Patents 324.5
291k324.5 Most Cited Cases

Determining whether particular device infringes properly construed patent claim is question of fact which Court of Appeals reviews for clear error on appeal from bench trial.

[23] Patents 226.6
291k226.6 Most Cited Cases

To prove patent infringement, patentee must show that accused device includes every limitation of asserted claim or equivalent of each limitation.

[24] Patents 168(2.6)
291k168(2.6) Most Cited Cases

In construing patent claims in view of prosecution history or in deciding whether to estop patentee from asserting certain range of equivalents, court may only explore reason (right or wrong) for objection and manner in which amendment addressed and avoided objection.

[25] Patents 168(2.6)
291k168(2.6) Most Cited Cases

When patent claim has been narrowed by amendment for substantial reason related to patentability, such as to avoid prior art rejection, patentee may not assert that surrendered subject matter is within range of equivalents.

[26] Patents 314(5)
291k314(5) Most Cited Cases

[26] Patents 324.5
291k324.5 Most Cited Cases

Application of prosecution history estoppel in patent infringement action is question of law subject to de novo review.

[27] Patents 97
291k97 Most Cited Cases

District court abused its discretion in finding that applicant for patent relating to recombinant DNA technology engaged in inequitable conduct before Patent and Trademark Office (PTO) by failing to disclose related European patent application, because, even if it was material, application was merely cumulative of materials already before PTO.

[28] Patents 97
291k97 Most Cited Cases

Even where patent applicant fails to disclose otherwise material prior art reference, that failure will not support finding of inequitable conduct if reference is simply cumulative to other references, such that reference teaches no more than what reasonable examiner would consider to be taught by prior art already before Patent and Trademark Office (PTO).

Patents 328(2)
291k328(2) Most Cited Cases

4,431,740. Not infringed.

Patents 328(2)
291k328(2) Most Cited Cases

4,652,525. Invalid.

Harold J. McElhinny, Morrison & Foerster LLP, San Francisco, CA, argued for plaintiff-appellant. With him on the brief were Donald S. Chisum, Alan K. Palmer, Rachel Krevans, and Debra A. Shetka. Also with him on the brief were Arthur I. Neustadt, Jean-Paul Lavalleye, Marc R. Labgold, and William J. Healey, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., Arlington, VA. Of counsel was Gladys H. Monroy, Morrison & Foerster LLP, San Francisco, CA.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., Washington, DC, argued for defendant-appellee. With him on the brief were Donald R. Dunner, Howard W. Levine, and John R. Alison. Of counsel on the brief was Amy E. Hamilton, Eli Lilly and Company, Indianapolis, IN.

Before NEWMAN, LOURIE, and BRYSON, Circuit Judges.

LOURIE, Circuit Judge.

The Regents of the University of California (UC) appeal from the judgment of the District Court for the Southern District of Indiana, holding that Eli Lilly & Company (Lilly) does not infringe U.S. Patent 4,652,525 or U.S. Patent 4,431,740 in its manufacture of human insulin; that the asserted claims of the '525 patent are invalid; and that both patents are unenforceable. *Regents of the Univ. of Cal. v. Eli Lilly and Co.*, 39 USPQ2d 1225 (S.D.Ind.1995). We hold that the district court (1) properly exercised jurisdiction over this case for trial on the merits, (2) did not err in concluding that the asserted claims of the '525 patent are invalid for failure to provide an adequate written description of the subject matter of the asserted claims, and (3) did not clearly err in finding that Lilly did not infringe the '740 patent. We further hold that the district court (4) abused its discretion in holding that the '525 and '740 patents are unenforceable. We therefore affirm-in-part and reverse-in-part.

BACKGROUND

In 1990, UC brought this action in the Northern District of California, alleging that Lilly was infringing claims 1, 2, and 4-7 of the '525 patent under the doctrine of equivalents and infringing claims 2-3, 5-6, 8-10, and 13- 14 of the '740 patent, either literally or under the doctrine of equivalents. Lilly responded that it does not infringe any of the asserted claims, that the asserted claims are invalid, and that the patents are unenforceable. Lilly did not assert any counterclaims against UC.

The patents in suit relate to recombinant DNA

technology [FN1] and, more specifically, to recombinant plasmids and microorganisms that produce human insulin, a protein involved in the regulation of sugar metabolism. A person unable to produce insulin is afflicted with diabetes. Prior to the development of recombinant techniques for the production of human insulin, diabetic patients were treated with injections of animal insulin, which often caused allergic reactions. Human insulin produced by recombinant methods is less likely to produce such reactions. It consists of two separate amino acid chains, a 21-amino acid A chain and a 30-amino acid B chain, which are linked only by disulfide bonds. Healthy people produce insulin *in vivo* via the terminal enzymatic cleavage of preproinsulin (PPI) to yield proinsulin (PI), a single amino acid chain consisting of the A and B chains, linked by a sequence of additional amino acids that positions the A and B chains so that the disulfide bonds are readily formed. The PI is then further cleaved to liberate the linking sequence and yield insulin.

FN1. For a detailed discussion of recombinant DNA technology, see *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207-08 n. 4, 18 USPQ2d 1016, 1022 n. 4 (Fed.Cir.1991) and *In re O'Farrell*, 853 F.2d 894, 895- 99, 7 USPQ2d 1673, 1674-77 (Fed.Cir.1988) and references therein.

The '525 patent, the application for which was filed in May 1977, was based upon the determination of the PI and PPI cDNA sequences found in *rats*. Claim 1 of that patent *1563 reads as follows: "A recombinant *plasmid* replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a *vertebrate*, which mRNA encodes insulin." (emphasis added). Claim 2 relates to a recombinant procaryotic *microorganism* containing *vertebrate* insulin-encoding cDNA. Claims 4 and 5 depend from claim 2, and are limited, respectively, to *mammalian* and *human* insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain "at least one genetic determinant of the plasmid col E1." Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

The '740 patent, the application for which was filed in September 1979, was based upon the determination of *human* PPI and PI cDNA sequences and the development of "tailoring" techniques for the incorporation of human PI cDNA into a recombinant plasmid. Using these techniques, a specific semi-synthetic DNA may be incorporated into a suitable transfer vector. Using one such tailoring technique, the human PI cDNA and the plasmid into which it is incorporated may be modified so that they contain complimentary oligo-dC and oligo-dG ends, which facilitate the formation of the recombinant plasmid. Independent claim 2 of the '740 patent reads: "A DNA transfer vector *comprising* an inserted cDNA *consisting essentially of* a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide of the sequence coding for said proinsulin." (emphasis added). Dependent claim 3 is directed, *inter alia*, to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector *comprising* a deoxynucleotide sequence coding for human proinsulin *consisting essentially of* a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." (emphasis added). Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

Lilly makes human PI using a semi-synthetic DNA to yield a cleavable *fusion protein* [FN2] that consists of a bacterial protein, a "cleavable linkage" consisting of a single methionine residue, and human PI. After the fusion protein is produced, the desired human PI is obtained by cleaving it from the remainder of the fusion protein.

FN2. For a detailed discussion of fusion proteins, see *Schendel v. Curtis*, 83 F.3d 1399, 1400 & n. 3, 38 USPQ2d 1743, 1744 & n. 3 (Fed.Cir.1996).

In 1992, pursuant to 28 U.S.C. § 1407 (1994), the Judicial Panel on Multidistrict Litigation (JPML) consolidated this case with five other related cases for pre-trial proceedings in the District Court for the Southern District of Indiana. *In re Recombinant DNA Tech. Patent and Contract Litig.*, No. 912 (J.P.M.L. Feb. 19, 1992). UC petitioned this court

for a writ of mandamus, seeking to vacate the transfer order as barred by the Eleventh Amendment and inconsistent with various prior decisions in the consolidated cases, including two decisions of the District Court for the Northern District of California in this case. *See In re Regents of the Univ. of Cal.*, 964 F.2d 1128, 1131-32, 22 USPQ2d 1748, 1751-52 (Fed.Cir.1992). We denied UC's petition, holding that the transfer did not force unconsented suit upon UC and thus was permissible for purposes of pretrial discovery. *Id.* at 1134, 964 F.2d 1128, 22 USPQ2d at 1754.

In 1994, responding to Lilly's pretrial motion, the District Court for the Southern District of Indiana transferred venue to itself for trial on the merits pursuant to 28 U.S.C. § 1404(a) (1994). After conducting a bench trial, the court issued a memorandum opinion in which it ruled, *inter alia*, that (1) Lilly does not infringe the asserted claims of either patent, 39 USPQ2d at 1228-39, (2) the asserted claims of the '525 patent, those directed *1564 to mammalian, vertebrate, and human cDNA, are invalid for lack of an adequate written description, *id.* at 1239-41, and (3) both patents are unenforceable due to inequitable conduct on the part of UC, *id.* at 1247-58. UC appeals from these rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

A. *Jurisdiction and Venue*

[1] As a preliminary matter, UC argues that the District Court for the Southern District of Indiana lacked jurisdiction to hear this case on the merits and was an inappropriate venue for trial. UC first argues that the Eleventh Amendment deprives the Indiana court of jurisdiction. Specifically, UC asserts that by choosing to bring suit in the District Court for the Northern District of California, it waived its Eleventh Amendment immunity only in California federal courts. Relying on *Port Authority Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 307, 110 S.Ct. 1868, 1873-74, 109 L.Ed.2d 264 (1990), UC argues that the Eleventh Amendment bars the transfer of this case for trial on the merits. Lilly responds that the Eleventh Amendment is inapplicable where, as here, a state asserts a claim and no counterclaim against the state is involved. We agree with Lilly that the Eleventh Amendment does not preclude trial in Indiana.

The Eleventh Amendment provides that: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. Const. amend. XI. The Supreme Court has recently confirmed that "the reference to actions 'against one of the United States' encompasses not only actions in which a State is named as a defendant, but also certain actions against state agents and state instrumentalities," such as UC. *Regents of the Univ. of Cal. v. Doe*, 519U.S. 425, —, 117 S.Ct. 900, 903, 137 L.Ed.2d 55 (1997); *see also BV Eng'g v. Univ. of Cal.*, 858 F.2d 1394, 1395, 8 USPQ2d 1421, 1422 (9th Cir.1988).

The question raised by this case is whether it is one that has been brought "against" UC. In deciding this question, we are aided by the Supreme Court's guidance in its opinion in *United States v. Peters*, 9 U.S. (5 Cranch) 115, 3 L.Ed. 53 (1809) (Marshall, C.J.). In that case, the Court declined to apply the Eleventh Amendment to bar a suit instituted against the heirs of a deceased state treasurer. The Court stated:

> The right of a state to assert, as plaintiff, any interest it may have in a subject, which forms the matter in controversy between individuals, in one of the courts of the United States, is not affected by [the Eleventh] amendment; nor can [the amendment] be so construed as to oust the court of its jurisdiction, should such claim be suggested. The amendment simply provides, that no suit shall be commenced or prosecuted against a state. The state cannot be made a defendant to a suit brought by an individual; but it remains the duty of the courts of the United States to decide all cases brought before them by citizens of one state against citizens of a different state, where a state is not necessarily a defendant.

Id. at 139. This case involves a state's assertion of a claim rather than a state being a defendant.

In the *Feeney* case relied on by UC, the Court applied the Eleventh Amendment because a claim for damages was asserted "against" a state instrumentality. The *Feeney* Court noted that "a State's Constitutional immunity encompasses not merely *whether* it may be sued, but *where* it may be sued," 495 U.S. 299, 307, 110 S.Ct. 1868, 1873-74, 109 L.Ed.2d 264 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 99, 104 S.Ct. 900, 907, 79 L.Ed.2d 67 (1984)), but the Court did not construe the Eleventh Amendment to apply to suits in which a state is solely a plaintiff, as UC is here. In fact, we do not believe that the Court has ever so construed the Eleventh Amendment. This is because

the Eleventh Amendment applies to suits "against" a state, not suits by a state. Thus, we need not determine whether UC waived its immunity only in California, because this case does not create an Eleventh *1565 Amendment jurisdictional issue concerning which the question of waiver even arises. This case only involves UC's patent infringement claims and Lilly's defenses; it does not involve any claim or counterclaim *against* UC that places UC in the position of a defendant. Accordingly, we conclude that the Eleventh Amendment does not deprive the Indiana district court of jurisdiction in this case.

[2] UC next argues that, under the law of the regional circuit to which appeal from the trial court would normally lie, the Indiana court abused its discretion by, as the court stated, transferring venue for trial on the merits from the California court to itself. *See* Heller Fin., Inc. v. Midwhey Powder Co., 883 F.2d 1286, 1293 (7th Cir.1989) (applying the abuse of discretion standard of review); Lou v. Belzberg, 834 F.2d 730, 739 (9th Cir.1987) (same). Specifically, UC argues that the Indiana court abused its discretion by, *inter alia,* affording too much weight to the element of judicial economy in granting Lilly's motion to transfer the case to Indiana. [FN3] Lilly responds that the court acted within its discretion by retaining the case for trial and that it properly considered and weighed the relevant factors before deciding to do so.

> FN3. UC also argues that the Indiana court abused its discretion by erroneously determining that UC could have brought this suit in Indiana without the state of California's consent, by overruling inconsistent decisions of the California district court, and by failing to give special weight to UC's choice of forum. We have considered these arguments and do not find them to be persuasive.

[3] We agree with Lilly that the court did not err on this point. A federal district court may "[f]or the convenience of parties and witnesses, in the interest of justice, ... transfer any civil action to any other district court or division where it might have been brought." 28 U.S.C. § 1404(a) (1994). The Indiana court based its decision to retain the case for trial on the merits on its finding that, although the convenience of the parties and witnesses did not favor either the Indiana or the California court, the interests of judicial economy would be served by trial in the Indiana court. Consideration of the interest of justice, which includes judicial economy, "may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result." Coffey v. Van Dorn Iron Works, 796 F.2d 217, 220-21 (7th Cir.1986); Allen v. Scribner, 812 F.2d 426, 436-37 (9th Cir.1987) ("Because the transfer of this case undoubtedly would have led to delay, the district court did not abuse its discretion in denying Allen's motion notwithstanding possible inconvenience to the witnesses."); Commodity Futures Trading Comm'n v. Savage, 611 F.2d 270, 279 (9th Cir.1979) (affirming denial of transfer motion because "[t]he district court was familiar with the case and transfer may have led to delay"). Thus, the fact that the district court ultimately afforded little or no weight to the other factors does not, standing alone, indicate that the district court abused its discretion. On the contrary, in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial economy may favor transfer to a court that has become familiar with the issues. Accordingly, the court did not abuse its discretion by transferring the case after affording determinative weight to the consideration of judicial economy.

[4] In its reply brief, UC first raises another basis for determining that Indiana was an improper venue for trial. UC argues that 28 U.S.C § 1407(a) (1994) requires that a case transferred by the JPML for consolidated pretrial proceedings be returned for trial on the merits to the court from which it was transferred. Aware that it failed to address this issue in its opening brief in this appeal, UC contends that it adequately raised this argument when it filed its petition for mandamus seeking to vacate the transfer order for consolidation of discovery in Indiana. *See* In re Regents, 964 F.2d 1128, 22 USPQ2d 1748. Lilly first responds that UC waived this argument by failing to raise it in its opening brief in this appeal, regardless of the argument it made in its earlier petition. Lilly also maintains that the transfer was lawful, citing *1566 *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation*, 102 F.3d 1524 (9th Cir.1996), *cert. granted sub nom.*, Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 520 U.S. 1227, 117 S.Ct. 1818, 137 L.Ed.2d 1026, 65 U.S.L.W. 3761 (1997) (No. 96-1482), for the proposition that § 1407(a) does not prohibit a discovery transferee court from transferring a case to itself for trial if an adequate reason for that transfer exists under 28 U.S.C. § 1404(a) (1994).

We agree with Lilly insofar as it argues that UC waived its argument regarding § 1407 by failing to raise it in its opening brief in this appeal. *See* Fed. R.App. P. 28(a)(6), 28(c); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800, 17 USPQ2d 1097, 1103 (Fed.Cir.1990) ("[A]n issue not raised by an appellant in its opening brief ... is waived."). UC's assertion that it adequately raised this argument when it filed its petition for mandamus is not persuasive. In denying that petition, we noted that UC expressed concern that, *inter alia*, "Lilly will maneuver to try the merits of the California actions in Indiana ... thus defeating [UC's] expectation and entitlement that the merits of the California actions will be tried in California." *In re Regents*, 964 F.2d at 1133, 22 USPQ2d at 1753. However, we declined to address UC's concern then because "[t]hese possibilities can not be evaluated in the abstract." *Id.* An assertion that the district court had actually erred was required, not the mere assertion that UC feared a potential error. We thus told UC that if it desired to contest the Indiana court's self-transfer, it would be required to raise that issue if and when the Indiana court actually transferred the case to itself. Because UC failed to do so by asserting error in a writ of mandamus or in its opening brief in this appeal, we decline to address the merits of its argument. Having determined that the Indiana court had jurisdiction and that its transfer of venue to itself under § 1404 was not, given the arguments properly before us, an abuse of that court's discretion, we address the remaining issues in UC's appeal.

B. *The '525 Patent*

1. *Validity*

The district court ruled that all of the claims of the '525 patent that UC asserted against Lilly, *viz.*, claims 1, 2, and 4-7, are invalid under § 112, ¶ 1, because the specification, although it provided an adequate written description of rat cDNA, did not provide an adequate written description of the cDNA required by the asserted claims. 39 USPQ2d at 1239-41.

[5][6][7] Whether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact, which we review for clear error on appeal from a bench trial. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed.Cir.1991); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed.Cir.1985). To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed.Cir.1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

[8] An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir.1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is *1567 required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

[9] We first consider claim 5, which is specific to a microorganism containing a human insulin cDNA. UC argues that the district court clearly erred in finding that claim 5 is invalid under § 112, ¶ 1. Specifically, UC argues that a constructive or prophetic example in the '525 specification describes in sufficient detail how to prepare the claimed organism. Lilly responds that the district court properly applied the written description requirement, as this court applied it in *Fiers*, 984 F.2d at 1170-71, 25 USPQ2d at 1605-06, and thus did not clearly err in finding that the cDNA encoding human insulin required by claim 5 is not adequately described in the '525 patent.

Claim 5 is directed to a recombinant procaryotic microorganism modified so that it contains "a nucleotide sequence having the structure of the reverse transcript of an mRNA of a [human], which mRNA encodes insulin." Thus, the definition of the claimed microorganism is one that requires human insulin-encoding cDNA. The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example,

however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

As indicated, Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA. Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. *See, e.g., In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed.Cir.1993). Thus, *a fortiori*, a description that does *not* render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1. Because the '525 specification provides only a general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA. Accordingly, the district court did not err in concluding that claim 5 is invalid for failure to provide an adequate written description.

[10] UC also argues that the district court erred in holding claims 1 and 2, which *generically* recite cDNA encoding vertebrate insulin, and claim 4, which is directed *generically* to cDNA encoding mammalian insulin, invalid. Dependent claims 6 and 7 similarly recite cDNA encoding vertebrate insulin. In support of this argument, UC cites the disclosure of a species (the rat insulin-encoding cDNA) within the scope of those generic claims. UC argues, citing *1568*In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (Cust. & Pat.App. 1976) and *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed.Cir.1988), that because the '525 specification meets the requirements of § 112, ¶ 1, for a species within both of these genera, the specification necessarily also describes these genera. Lilly responds that the district court did not clearly err in finding that cDNA encoding mammalian and vertebrate insulin were not adequately described in the '525 patent, because description of one species of a genus is not necessarily a description of the genus.

[11] We agree with Lilly that the claims are invalid. Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (Cust. & Pat.App.1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus....").

The cases UC cites in support of its argument do not lead to the result it seeks. These cases do not compel the conclusion that a description of a species always constitutes a description of a genus of which it is a part. These cases only establish that every species in a genus need not be described in order that a genus meet the written description requirement. *See Utter*, 845 F.2d at 998-99, 6 USPQ2d at 1714 ("A specification may, within the meaning of § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim

encompasses.") (affirming board's finding that an application that "describes in detail the geometry and components that make its *internal* pivot embodiment work" also sufficiently describes an interference count that is "silent as to the location of the pivot"). In addition, *Angstadt* is an enablement case and *Utter* involves machinery of limited scope bearing no relation to the complex biochemical claims before us.

[12] In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *See Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed.Cir.1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

[13] Thus, as we have previously held, a cDNA is not defined or described by the *1569 mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. *See Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. [FN4] This is analogous to enablement of a genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus. *See Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (Cust. & Pat.App.1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide an implicit description upon which to base generic claim language."); *Cf. Gosteli*, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (Cust. & Pat.App.1960) ("[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.' ") (citations omitted). We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

> FN4. We note that in claims 4, 5, and 12-14 of the '740 patent, genera of DNA sequences encoding human PI or PPI are described by reference to the structure of the claimed DNA sequences rather than by reference to their function.

Accordingly, we reject UC's argument that the

district court clearly erred in finding claims 1, 2, 4, 6, and 7 invalid for failure to provide an adequate written description. Because we affirm the district court's ruling that all of the claims of the '525 patent asserted against Lilly are invalid, we need not consider whether Lilly infringed those claims. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319 (Fed.Cir.1996).

2. *Enforceability*

[14] The district court also ruled the '525 patent unenforceable on the ground of inequitable conduct. The court based this ruling on its findings that UC had violated National Institutes of Health (NIH) guidelines in order to develop the patented invention as soon as possible and had falsified material in its patent application in an effort to disguise its violation. The court noted that at the time the application that became the '525 patent was filed, NIH had certified only three plasmids for use with mammalian DNA: pSC101, pCR1, and pMB9. 39 USPQ2d at 1249. It then found that UC researchers knowingly used the uncertified pBR322 plasmid to hasten their determination of the rat PI and PPI cDNA sequences, and misrepresented that they had used pMB9, a certified plasmid, in the actual examples of their patent application. The court also found that a reasonable patent examiner would have viewed this misrepresentation as material to patentability. *Id.* at 1254.

UC argues that we should reverse the district court's ruling because it is based on a misinterpretation of the applicable law on inequitable conduct. Specifically, UC argues that the district court improperly considered alleged misrepresentations made to the NIH and Congress, and failed to properly consider *1570 whether the alleged misrepresentation in the patent application regarding the use of pMB9 was material to patentability. UC also argues that the district court clearly erred in finding that UC actually used pBR322 and then misrepresented that it used pMB9. In response, Lilly argues that under *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 30 USPQ2d 1149 (Fed.Cir.1994), UC's misrepresentation was sufficient to support a finding of inequitable conduct, and that such a misrepresentation need not bear directly on patentability as long as that misrepresentation was made in an effort to obtain a patent more quickly than otherwise. Lilly also argues that the district court properly found that UC's alleged pattern of deceit before a variety of governmental bodies was sufficient to render the patent unenforceable under the broad doctrine of "unclean hands." *See, e.g., Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 54 S.Ct. 146, 78 L.Ed. 293, 19 USPQ 228 (1933).

[15][16] "A determination of inequitable conduct is committed to a district court's discretion. Accordingly, we review the district court's judgment for an abuse of discretion." *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1541, 41 USPQ2d 1829, 1834 (Fed.Cir.1997) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed.Cir.1988)). To overturn a discretionary ruling of a district court, "the appellant must establish that the ruling is based on clearly erroneous findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1827 (Fed.Cir.1995).

[17] We conclude that the district court abused its discretion in holding the '525 patent to be unenforceable. An infringer asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney either failed to disclose material information or submitted false material information to the Patent and Trademark Office (PTO) and that the applicant or his attorney did so with an intent to deceive the PTO. *See Kingsdown*, 863 F.2d at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed.Cir.1984).

The alleged misinformation submitted to the PTO in this case consists of statements in Examples 4 and 5 of the specification that the pMB9 plasmid was used as the cloning vector for the rat cDNA when pBR322 appears to have been used. Lilly does not argue that the pMB9 plasmid was inoperable in the stated examples, only that Examples 4 and 5 should not have been stated as actual examples (even though they presumably could have been stated as constructive, *i.e.*, hypothetical, examples). Accordingly, Lilly must demonstrate that this distinction would have been considered material by a reasonable patent examiner. We conclude that it has not done so by clear and convincing evidence.

There is no reason to believe that a reasonable examiner would have made any different decision if

UC had framed Examples 4 and 5 as constructive examples. *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1578, 224 USPQ 409, 415 (Fed.Cir.1984) ("Even if intent could be inferred, and if the examples were constructive but not disclosed to the examiner as such, [the alleged infringer] has not shown the nondisclosure to have been material, *i.e.*, important to an examiner in allowing the patent to issue."); Manual of Patenting Examining Procedure (MPEP) § 707.07(*l*) (5th ed. 1993) ("The results of the tests and examples should not normally be questioned by the examiner unless there is a reasonable basis for questioning the results."); *cf.* Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808-09, 15 USPQ2d 1481, 1484 (Fed.Cir.1990) (affirming a finding of inequitable conduct based on an applicant's intentional disclosure of a "fictitious, inoperable" example and withholding of a best mode.). Moreover, the examiner would not have made any different decision if pBR322, the plasmid the district court found was actually used, was recited in the examples, because, as the record shows, the procedures described *1571 in Examples 4 and 5 for rat insulin cDNA worked to yield the intended results irrespective of whether pMB9 or pBR322 was used. The misidentification of the plasmid was therefore not material to patentability. Thus, no inequitable conduct occurred in the procurement of the patent.

In addition, contrary to the findings of the district court, a reasonable patent examiner would not have considered non-compliance with the NIH guidelines to be material to patentability. The district court based its finding of materiality on the theory that if the applicant had complied with the guidelines, the application might have been delayed and the applicants might not have been the first to apply for a patent on the claimed subject matter. However, such unfounded speculation is not clear and convincing evidence of materiality.

General Electro Music does not support Lilly's argument that UC's failure to have actually used pMB9 would have been material to patentability. In General Electro Music, we concluded that "a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent." 19 F.3d at 1411, 30 USPQ2d at 1154. We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." *Id.* As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. UC got no advantage in the patent examining process. Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability.

[18] We also reject Lilly's alternative argument that the patent is unenforceable under the doctrine of "unclean hands." This court has previously refused to afford equitable relief in that guise in the absence of proof of materiality. In J.P. Stevens, 747 F.2d at 1560 n. 7, 223 USPQ at 1093 n. 7, we rejected the argument that "unclean hands" could render a patent unenforceable without proof of materiality because such a "categorization is inconsistent with this court's view that materiality is a necessary ingredient of any inequitable conduct." Accordingly, there is no legal basis for the conclusion that inequitable conduct occurred in the procurement of the patent and the district court therefore abused its discretion in its conclusion that the patent was unenforceable.

C. *The '740 Patent*

1. *Infringement*

[19] The district court ruled that Lilly did not infringe claims 5-6 and 8- 10 of the '740 patent either literally or under the doctrine of equivalents, 39 USPQ2d at 1231-38, and did not infringe claims 2-3 and 13-14 of the '740 patent under the doctrine of equivalents, *id.* at 1238. After evaluating the specification and the prosecution history, and receiving extrinsic evidence, the court construed these claims to be limited to genetic constructs (*i.e.*, "plasmids" and "transfer vectors") and microorganisms from which human PI is directly expressed. Accordingly, the court found that Lilly, which does not make or use such constructs or microorganisms, but expresses a recombinant fusion protein that is later cleaved to yield human PI, did not literally infringe the asserted claims. The court further determined that Lilly did not infringe the claims under the doctrine of equivalents because claim amendments made during the prosecution of the patent application bar UC from successfully asserting that the materials Lilly uses for expressing a recombinant fusion protein are equivalent to the claims of the '740 patent.

Challenging the district court's finding of a lack of literal infringement, UC argues that the district court incorrectly interpreted the claims. Specifically, UC argues that the use of the term "comprising" in the

claims indicates that a transfer vector such as that used by Lilly will infringe the claims as long as it includes the inserted cDNA encoding human PI, irrespective of the presence of other elements such as the DNA encoding the remainder of Lilly's fusion protein. Lilly responds that the district court correctly interpreted the claims in light of the prosecution history. Lilly argues that a prior art *1572 rejection was based on the examiner's conclusion that the prior art taught how to make recombinant insulin as part of a fusion protein and that UC therefore obtained allowance of the claims by specifically disclaiming transfer vectors that encode fusion proteins.

[20][21][22][23] A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1576, 27 USPQ2d 1836, 1839 (Fed.Cir.1993). The first step, claim construction, is a question of law which we review *de novo;* the proper construction of the claims is based upon the claim language, the specification, the prosecution history, and if necessary to aid the court's understanding of the patent, extrinsic evidence. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81, 34 USPQ2d 1321, 1329-31 (Fed.Cir.1995) (in banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577, 38 USPQ2d 1461 (1996). The second step, determining whether a particular device infringes a properly construed claim, is a question of fact which we review for clear error on appeal from a bench trial. *See* Fed.R.Civ.P. 52(a); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed.Cir.1983). In order to prove infringement, a patentee must show that "the accused device includes every limitation of the [asserted] claim or an equivalent of each limitation." *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 397, 29 USPQ2d 1767, 1769 (Fed.Cir.1994).

We agree with Lilly that UC surrendered coverage of DNA that encodes a fusion protein. The district court correctly interpreted the asserted claims to be limited to genetic constructs and microorganisms that do not include DNA coding for a fusion protein. UC argues that the direct expression of human PI and the expression of human PI via a fusion protein are both described in the patent as part of the invention of the '740 patent, but that fact doesn't change the prosecution history which indicates that UC surrendered coverage of the latter in order to overcome prior art.

[24] This surrender is best exemplified by the prosecution history relating to the claims that ultimately issued as claims 2 and 5. These claims as originally filed were directed, with varying degrees of specificity, to a DNA transfer vector *comprising* a DNA sequence coding for human PI. The word "comprising," as UC argues and as is well-established, permits inclusion of other moieties. However, during the prosecution of the patent, the examiner rejected these claims as unpatentable based on, *inter alia*, Ullrich *et al.*, 196 Science 1313 (June 17, 1977) and Villa-Komaroff *et al.*, 75 PNAS 3727 (August 1978). [FN5] The district court, essentially repeating the statements made by the patent examiner during the prosecution of the patent, found that these references taught, [FN6] respectively, the need "to combine the genetic information for the eukaryotic insulin gene with prokaryotic regulatory sequences, to obtain expression of insulin in bacteria," and "a general method for the expression and secretion of any eukaryotic protein [such as human PI] provided another protein ... will *1573 serve as a carrier [as part of a fusion protein], by virtue of its leader sequence." 39 USPQ2d at 1232. The examiner thus rejected the claims because he believed that the prior art taught the use of recombinant eukaryotic/procaryotic fusion proteins for the production of a eukaryotic protein, including insulin, in a recombinant bacterium.

FN5. Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in the production of human PI. *See* 39 USPQ2d at 1231 n. 12. For the sake of brevity, we do not discuss them here.

FN6. UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be revisited in an infringement action." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, --- U.S. ---, --- n. 7, 117 S.Ct. 1040, 1051 n. 7, 137 L.Ed.2d 146, 41

USPQ2d 1865, 1872-73 n. 7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." *Id.* Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history.

In an effort to overcome the rejection based on these references, UC first amended claim 2 to read, in pertinent part: "A DNA transfer vector comprising an inserted cDNA *having* a[DNA] sequence coding for human [PI]...." The word "having" still permitted inclusion of other moieties. When again confronted by a rejection based upon the same references and a later requirement that the word "having" be changed to "consisting essentially of," a narrower term, UC ultimately complied by amending claim 2 to its present form, *viz.*, "A DNA transfer vector comprising an inserted cDNA *consisting essentially of* a[DNA] sequence coding for human [PI]." Similarly, UC amended claim 5 to its present form, which reads, in pertinent part: "A DNA transfer vector comprising a[DNA] sequence coding for human [PI] *consisting essentially of* a plus strand having the sequence ...." (emphasis added). The examiner allowed these claims, noting that the required "consisting essentially of" language "excludes from the cDNA the presence of sequences other than [those coding for PI]." We agree with the district court that UC thus narrowed its claims in response to a prior art rejection to exclude the materials producing a fusion protein, as Lilly now does. UC urges us to read the examiner's statement on allowance of the claims narrowly as pertaining only to claim 2 and to exclude only DNA other than naturally-occurring human cDNA. However, that statement is not so limited; it expressly applies to claim 5 and, moreover, reflects the examiner's consistent requirement, acquiesced in by UC, that the DNA inserted in the claimed vectors code only for PI, not for a PI-containing fusion protein. [FN7]

FN7. UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement.

We have considered all of the other arguments made by UC, including its assertion that the examiner's rejections were based on a distinction between tailored and non-tailored cDNA, but find them to be unpersuasive. In light of the prosecution history, we agree with the district court that claims 5 and 6, which contain the language added during prosecution, cannot be construed to literally cover Lilly's expression of human PI via a fusion protein. Furthermore, UC has stated in its appeal brief that, for purposes of the analysis of literal infringement, the scope of claims 8-10 is no broader than that of claims 5 and 6, and that it does not appeal the court's finding with respect to claims 8-10. Accordingly, we affirm the district court's construction of claims 5-6 and 8-10; its factual finding that Lilly does not literally infringe claims 5-6 is not clearly erroneous and is therefore also affirmed.

Regarding the district court's application of the doctrine of equivalents, UC argues that the district court improperly interpreted the prosecution history to indicate that UC had disclaimed vectors encoding fusion proteins instead of to indicate, as properly interpreted, that the claims were limited to "tailored" cDNA inserts. However, as indicated above, we find no error in the district court's interpretation of the claims and the prosecution history and hence its conclusion that Lilly does not infringe the asserted claims under the doctrine of equivalents.

[25][26] When a claim has been narrowed by amendment for a "substantial reason related to patentability," such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, --- U.S. ---, ---- - ---, 117 S.Ct. 1040, 1049-51, 137 L.Ed.2d 146, 41 USPQ2d 1865, 1871-73 (1997); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1107, 40 USPQ2d 1602, 1609 (Fed.Cir.1996), *cert. denied*, 520 U.S. 1198, 117 S.Ct. 1555, 137 L.Ed.2d 703 (1997); ("Prosecution history estoppel *1574 bars the patentee from recapturing subject matter that was surrendered by the patentee during prosecution in order to promote allowance of the claims."). "The application of prosecution history estoppel is a question of law subject to *de novo* review." *Id.*; *see also Warner-Jenkinson*, --- U.S. at ---- - ----, 117 S.Ct. at 1049-51,

137 L.Ed.2d 146, 41 USPQ2d at 1871-73.

As the district court properly concluded, the above-described prosecution history estops UC's '740 patent from dominating Lilly's expression of its fusion protein. As a matter of law, the material used by Lilly for expressing its fusion protein is not equivalent to that of the above-analyzed claims, or to the materials of the other asserted claims, *i.e.*, claims 2-3 and 13-14, for such an application of the doctrine of equivalents would allow UC to recapture subject matter it surrendered during the prosecution of the '740 patent. Accordingly, UC cannot meet its burden of establishing infringement under the doctrine of equivalents. The district court did not clearly err in determining that Lilly did not infringe the '740 patent, either literally or under the doctrine of equivalents.

2. *Enforceability*

[27] The district court ruled that the '740 patent was unenforceable for inequitable conduct. 39 USPQ2d at 1255-58. The court based this ruling in part on its finding that UC failed to disclose to the PTO a highly-material reference, European Patent Application No. 1929 (EPA-1929), entitled "Plasmid for Transforming Bacterial Host to Render It Capable of Polypeptide Expression" in which the expression of human somatostatin and insulin are used as examples. [FN8] The court also based its ruling on its finding that UC was made aware of the materiality of EPA-1929 when it was cited as prior art by the European Patent Office (EPO) during the prosecution of the European counterpart of the application that led to the '740 patent. The court found that under these facts, it would "draw an inference of intent to mislead," *id.* at 1257, and accordingly, found that UC had engaged in inequitable conduct.

> FN8. This application was filed by Genentech, Inc. and named Drs. Itakura and Riggs as inventors.

UC argues that it did not have a duty to disclose EPA-1929 to the PTO because it was merely cumulative of the references it had submitted to the PTO. Specifically, UC argues that EPA-1929 was cumulative of the two references on which EPA-1929 was based, which were already before the examiner when UC became aware of EPA-1929: Goeddel *et al.*, 76 PNAS 3727 (1979) and Itakura *et al.*, 198 Science 1056 (1977). [FN9] UC also argues that the district court misapplied the law on inequitable conduct by inferring an intent to deceive when the uncited reference was merely cumulative. Lilly responds that EPA-1929 was not cumulative because, unlike the reference before the examiner, it described a specific, enabling technique for making "tailored" DNA that would encode for a fusion protein including human PI. Lilly argues that UC's assertions of subjective good faith amount to no more than a mere denial of bad faith and accordingly that the district court properly disregarded those assertions. We agree with UC that the district court clearly erred in finding that EPA-1929 was not cumulative and, accordingly, in inferring an intent to deceive.

> FN9. Drs. Itakura and Riggs, inventors of the EPA-1929 subject matter, are noted as authors on both of these articles.

[28] As stated above, we review a district court's ruling that a patent is unenforceable for inequitable conduct under an abuse of discretion standard. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed.Cir.1988). An infringer asserting an inequitable conduct defense must prove by clear and convincing evidence that the applicant or his attorney failed to disclose material information or submitted false material information to the PTO, with an intent to deceive the PTO. *See id.* at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed.Cir.1984). However, even where an applicant fails to disclose an otherwise material prior art reference, that failure will *1575 not support a finding of inequitable conduct if the reference is "simply cumulative to other references," *i.e.*, if the reference teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014 (Fed.Cir.1991).

The district court correctly found that UC knew of the materiality of EPA-1929 because the EPO considered EPA-1929 to be material to the examination of the European counterpart of the '740 patent. However, if EPA-1929 was merely cumulative of other references already before the examiner, UC's failure to cite it will not support a finding of inequitable conduct because one is justified in not submitting cumulative prior art. The

record indicates that EPA-1929 was cumulative. The examiner had already noted the relevance of both the Itakura article, entitled "Expression in *Escherichia coli* of Chemically Synthesized Gene for the Hormone Somatostatin," and the Goeddel article, entitled "Expression in *Escherichia coli* of Chemically Synthesized Genes for Human Insulin." As is suggested by their respective titles and their dates of publication and submission, the work described in the two articles is essentially the same as that described in EPA-1929. In fact, the record indicates that the European patent examiner cited EPA-1929 against the European counterpart of the '740 patent, but cited the Goeddel article merely to demonstrate the state of the art and did not cite the Itakura article at all.

Lilly argues that these articles are distinguishable from EPA-1929 based on the fact that EPA-1929 also includes a claim (claim 6) directed, in part, to a plasmid encoding human proinsulin. But the inclusion of a claim is not controlling in a determination whether EPA-1929 is cumulative. What is relevant is whether EPA-1929 discloses subject matter relevant to the examination of the '740 patent application that is not taught by the Goeddel and Itakura articles. Plainly it does not. The Goeddel article and EPA-1929 *describe* in similar detail the same experiments which led to the production of a recombinant human insulin/β-galactosidase fusion protein. That Genentech attempted to claim a plasmid encoding human proinsulin in EPA-1929 does not add to its disclosure compared with the Goeddel article. We therefore conclude that the district court clearly erred in finding that EPA-1929 was not cumulative.

Because we conclude that the district court's finding of materiality was clearly erroneous, we also necessarily conclude that the district court clearly erred in inferring deceptive intent from the mere fact that UC did not cite EPA-1929. UC's failure to disclose the EPA-1929 reference, given its cumulative nature, is not clear and convincing evidence of inequitable conduct. Because the district court's conclusion that the '740 patent is unenforceable for inequitable conduct is based on clearly erroneous findings of materiality and intent, that conclusion is reversed.

CONCLUSION

The district court properly exercised jurisdiction over this case and did not abuse its discretion in transferring the case to itself for a trial on the merits. It did not clearly err in finding that the '525 patent does not provide an adequate written description of the subject matter of the asserted claims and thus properly held that those claims are invalid, nor did it clearly err in finding that Lilly did not infringe the asserted claims of the '740 patent. The court abused its discretion in holding that the '525 and '740 patents are unenforceable. Accordingly, the decision of the district court is

AFFIRMED-IN-PART and *REVERSED-IN-PART.*

COSTS

Costs to Lilly.

119 F.3d 1559, 43 U.S.P.Q.2d 1398

Briefs and Other Related Documents (Back to top)

- 1996 WL 33419504 (Appellate Brief) Reply Brief for Plaintiff-Appellant the Regents of the University of California (Aug. 02, 1996)Original Image of this Document (PDF)
- 1996 WL 33419503 (Appellate Brief) Brief for Plaintiff-Appellant The Regents of the University of California (May. 09, 1996)Original Image of this Document with Appendix (PDF)
- 1996 WL 33419502 (Appellate Brief) Nonconfidential Brief for Defendant-Appellee Eli Lilly and Company (1996)Original Image of this Document (PDF)

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358 F.3d 916
358 F.3d 916, 185 Ed. Law Rep. 122, 69 U.S.P.Q.2d 1886
(Cite as: 358 F.3d 916)

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Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.

UNIVERSITY OF ROCHESTER, Plaintiff-Appellant,
v.
G.D. SEARLE & CO., INC., Monsanto Company, Pharmacia Corporation, and Pfizer Inc., Defendants-Appellees.

No. 03-1304.

Feb. 13, 2004.

Background: Owner of patent for method of treating inflammation without undesirable side effects sued drug manufacturer for infringement. The United States District Court for the Western District of New York, 249 F.Supp.2d 216, David G. Larimer, J., granted summary judgment of invalidity, and owner appealed.

Holding: The Court of Appeals, Lourie, Circuit Judge, held that patent did not satisfy written description requirement.

Affirmed.

West Headnotes

[1] **Patents** 112.5
291k112.5 Most Cited Cases

Issued patent enjoys presumption of validity that can be overcome only through clear and convincing evidence. 35 U.S.C.A. § 282.

[2] **Patents** 99
291k99 Most Cited Cases

Patent that claimed method of achieving biological effect, i.e., selective inhibition of inflammation-causing enzyme, but disclosed no compounds that could accomplish that result, was invalid for lack of written description, absent showing that such compounds were otherwise within knowledge of person of ordinary skill in art; patent disclosed nothing more than hoped-for function for as-yet-to-be-discovered compound, and research plan for trying to find it. 35 U.S.C.A. § 112, par. 1.

[3] **Patents** 98
291k98 Most Cited Cases

[3] **Patents** 99
291k99 Most Cited Cases

Statutory requirement that patent contain written description is distinct and independent from requirements that it disclose best mode and be enabling. 35 U.S.C.A. § 112, par. 1.

[4] **Statutes** 152
361k152 Most Cited Cases

[4] **Statutes** 174
361k174 Most Cited Cases

Statutory language does not become redundant unless repealed by Congress, in which case it no longer exists.

[5] **Patents** 99
291k99 Most Cited Cases

Generalized language in patent specification may not satisfy written description requirement if it does not convey detailed identity of invention. 35 U.S.C.A. § 112, par. 1.

[6] **Patents** 99
291k99 Most Cited Cases

Although description of actual reduction to practice is not necessary to satisfy written description requirement, patent specification must at least describe claimed subject matter in terms that establish that inventor was in possession of claimed invention, including all of its elements and limitations. 35 U.S.C.A. § 112, par. 1.

[7] **Patents** 112.1
291k112.1 Most Cited Cases

Statute placing burden of proof on party seeking to

invalidate patent does not foreclose possibility of that party demonstrating that patent in suit proves its own invalidity. 35 U.S.C.A. § 282.

Patents 328(2)
291k328(2) Most Cited Cases

5,837,479. Cited.

Patents 328(2)
291k328(2) Most Cited Cases

6,048,850. Invalid.

*917 Gerald P. Dodson, Morrison & Foerster, LLP, of Palo Alto, CA, argued for plaintiff-appellant. With him on the brief were Emily A. Evans, Erica D. Wilson, and Erik J. Olson. Of counsel on the brief was Jeanine Arden Ornt, Office of Counsel, University of Rochester, of Rochester, NY.

Gerald Sobel, Kaye Scholer LLP, of New York, NY, argued for defendants-appellees. With him on the brief were Richard G. Greco, Sylvia M. Becker, and Daniel L. Reisner. With him on the brief were Robert L. Baechtold, Henry J. Renk, Bruce C. Haas, and Colleen Tracy, Fitzpatrick, Cella, Harper & Scinto, of New York, NY.

Daniel J. Furniss, Townsend and Townsend and Crew LLP, of Palo Alto, CA, for amici curiae The Regents of the University of California, et al. With him on the brief were Susan M. Spaeth and Madison C. Jellins.

James J. Kelley, Eli Lilly and Company, of Indianapolis, IN, for amicus curiae Eli Lilly and Company. With him on the brief were Steven P. Caltrider, Michael T. Bates, Robert A. Armitage, Gilbert T. Voy, and Gregory C. Cox.

Before LOURIE, BRYSON, and DYK, Circuit Judges.

LOURIE, Circuit Judge.

The University of Rochester ("Rochester") appeals from the decision of the United States District Court for the Western District of New York granting summary judgment that United States Patent 6,048,850 is invalid. *Univ. of Rochester v. G.D. Searle & Co.*, 249 F.Supp.2d 216 (W.D.N.Y.2003). Because we conclude that the court did not err in holding the '850 patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment on that ground, we affirm.

BACKGROUND

Traditional non-steroidal anti-inflammatory drugs ("NSAIDs") such as aspirin, ibuprofen, ketoprofen, and naproxen are believed to function by inhibiting the activity of enzymes called cyclooxygenases. Cyclooxygenases catalyze the production of a molecule called prostaglandin H2, which is a precursor for other prostaglandins that perform various functions in the human body. *Id.* at 219.

In the early 1990s, scientists discovered the existence and separate functions of two distinct cyclooxygenases, referred to as "COX-1" and "COX-2." [FN1] COX-1 is expressed (*i.e.*, produced biologically) in the gastrointestinal tract, where it is involved in the production of prostaglandins that serve a beneficial role by, for example, providing protection for the stomach lining. *Id.* COX-2 is expressed in response to inflammatory stimuli, and is thought to be responsible for the inflammation associated with diseases such as arthritis. *Id.* It is now known that the traditional NSAIDs inhibit both COX-1 and COX-2, and as a result they not only reduce inflammation, *918 but also can cause undesirable side effects such as stomach upset, irritation, ulcers, and bleeding. *Id.*

FN1. COX-1 and COX-2 are alternatively referred to as "PGHS-1" and "PGHS-2," respectively, where "PGHS" is an abbreviation for "prostaglandin H synthase."

After the separate functions of COX-1 and COX-2 were discovered, it was hypothesized that it would be possible to reduce inflammation without gastrointestinal side effects if a method could be found for selectively inhibiting the activity of COX-2 (*i.e.*, inhibiting the activity of COX-2 without inhibiting COX-1 activity). *Id.* To that end, Rochester scientists developed a screening assay for use in determining whether a particular drug displayed such selectivity, and filed a U.S. patent application directed to their developments in 1992. After filing a series of continuation, continuation-in-part, and divisional applications derived from that 1992 application, the scientists eventually received

United States Patent 5,837,479 in 1998, covering methods "for identifying a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2)."

From a division of the application that led to the '479 patent, the scientists also obtained, on April 11, 2000, the '850 patent. The '850 patent contains three independent claims and five dependent claims. The three independent claims read as follows:

1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

5. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the activity of the non-steroidal compound does not result in significant toxic side effects in the human host.

6. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS 2 gene product in a human host in need of such treatment, wherein the ability of the non-steroidal compound to selectively inhibit the activity of the PGHS-2 gene product is determined by:

a) contacting a genetically engineered cell that expresses human PGHS-2, and not human PGHS-1, with the compound for 30 minutes, and exposing the cell to a pre-determined-amount of arachidonic acid;

b) contacting a genetically engineered cell that expresses human PGHS-1, and not human PGHS-2, with the compound for 30 minutes, and exposing the cell to a pre-determined amount of arachidonic acid;

c) measuring the conversion of arachidonic acid to its prostaglandin metabolite; and

d) comparing the amount of the converted arachidonic acid converted by each cell exposed to the compound to the amount of the arachidonic acid converted by control cells that were not exposed to the compound, so that the compounds that inhibit PGHS-2 and not PGHS-1 activity are identified.

'850 patent, col. 71, l. 36—col. 72, l. 51. Thus, all eight claims are directed to methods "for selectively inhibiting PGHS-2 activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment."

On the day the '850 patent issued, Rochester sued G.D. Searle & Co., Inc., Monsanto *919 Co., Pharmacia Corp., and Pfizer Inc. (collectively, "Pfizer"), alleging that Pfizer's sale of its COX-2 inhibitors Celebrex® and Bextra® for treatment of inflammation infringed the '850 patent. [FN2] and seeking injunctive and monetary relief. *Univ. of Rochester*, 249 F.Supp.2d at 220. In May 2002, Pfizer moved for summary judgment of invalidity of the '850 patent for failure to comply with the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1. Rochester opposed the motion and filed a cross-motion for summary judgment with respect to the written description issue. *Id.*

FN2. Celebrex® and Bextra®, generically known as celecoxib and valdecoxib, respectively, were both developed by Searle, which was purchased by Monsanto in 1985. In 2000, Monsanto merged with Pharmacia & Upjohn, Inc. to form Pharmacia Corp. In 2002, Monsanto, sans Searle, was spun off from Pharmacia, and Pharmacia merged with Pfizer in 2003. The combined company has retained the name Pfizer Inc.

In evaluating the parties' motions, the district court found that, although all of the claims require the use of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene," the '850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research. *Id.* at 224- 25, 228-29. Indeed, the court found no evidence in the '850 patent that the inventors themselves knew of any such compound at the time their patent application was filed. *Id.* at 228. Accordingly, the court concluded that the patent's claims are invalid for lack of written description. *Id.* at 224.

The district court also found that practice of the claimed methods would require "a person of ordinary skill in the art ... to engage in undue experimentation, with no assurance of success," and on that basis concluded that the claims are also invalid for lack of enablement. *Id.* at 232. The court considered, but rejected as conclusory, Rochester's experts' opinions that one of skill in the art would have known to start with existing NSAIDs and would have used routine methods to make structural changes to lead

compounds to optimize them, citing a general failure to point to any language in the patent supporting those opinions. *Id.* at 233.

Finding no genuine issue of material fact concerning either written description or enablement, the district court accordingly granted Pfizer's motions for summary judgment of invalidity of the '850 patent for failure to meet the written description and enablement requirements, denied Rochester's cross-motion, and dismissed the complaint. *Id.* at 235-36.

Rochester now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Rochester asserts three grounds of error on appeal. First, it argues that the district court erred by granting Pfizer's motion for summary judgment of invalidity for lack of written description. Second, it argues that the court erred by granting Pfizer's motion for summary judgment of invalidity for lack of enablement. Third, Rochester contends that the court erred by denying its cross-motion for summary judgment with regard to written description. Pfizer refutes each of those asserted grounds of error.

Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1353 (Fed.Cir.1998). We review a district court's grant of summary judgment *de novo*, reapplying *920 the summary judgment standard. *Conroy v. Reebok Int'l*, 14 F.3d 1570, 1575 (Fed.Cir.1994). In contrast, "when a district court *denies* summary judgment, we review that decision with considerable deference to the court," and "will not disturb the trial court's denial ... unless we find that the court has indeed abused its discretion in so denying." *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1333 (Fed.Cir.1999). Additionally, "[w]hen evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed.Cir.2001) ("*Barr* "). In that process, we draw all justifiable inferences in the nonmovant's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

[1] An issued patent enjoys a presumption of validity, 35 U.S.C. § 282, that can be overcome only through clear and convincing evidence, *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563 (Fed.Cir.1997). Accordingly, a party "seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity." *Barr*, 251 F.3d at 962.

[2] In its first argument, Rochester asserts that the district court effectively--but erroneously--held that a patent claiming a method of obtaining a biological effect in a human by administering a compound cannot, as a matter of law, satisfy the written description requirement without disclosing the identity of any such compound. Indeed, Rochester contends that "no written description requirement exists independent of enablement." In any event, Rochester argues that its patent met the requirements of § 112 and is not invalid. [FN3]

> FN3. Rochester is supported by *amici curiae* the Regents of the University of California, the University of Texas Southwestern Medical Center at Dallas, and the University of Texas M.D. Anderson Cancer Center, which make essentially the same points.

Pfizer responds to Rochester's argument by pointing out that we have "interpreted § 112 'as requiring a "written description" of an invention separate from enablement,' " (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed.Cir.2002)), and that "the many prior precedential decisions" contrary to Rochester's position "cannot be overruled except by an *en banc* decision." Pfizer also cites *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed.Cir.1991), in which we explained that "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]," *id.* at 1563; and *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed.Cir.2000), in which we stated that the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification," *id.* at 1345. Pfizer asserts that a patent fails to satisfy the written description requirement if it claims a method of achieving a biological effect, but discloses no compounds that can accomplish that result. It maintains that the district court correctly invalidated Rochester's '850 patent. [FN4]

FN4. Pfizer is supported by *amicus curiae* Eli Lilly & Co., which makes similar arguments.

We agree with Pfizer that our precedent recognizes a written description requirement and that the '850 patent does not satisfy that requirement. As in any case involving statutory interpretation, we begin *921 with the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108, 100 S.Ct. 2051, 64 L.Ed.2d 766 (1980). Section 112 provides, in relevant part, that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (2000). Three separate requirements are contained in that provision: (1) "[t]he specification shall contain a written description of the invention"; (2) "[t]he specification shall contain a written description ... of the manner and process of making and using it [*i.e.*, the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same"; and (3) "[t]he specification ... shall set forth the best mode contemplated by the inventor of carrying out his invention."

[3] In common parlance, as well as in our and our predecessor court's case law, those three requirements are referred to as the "written description requirement," the "enablement requirement," and the "best mode requirement," respectively. *See In re Moore*, 58 C.C.P.A. 1042, 439 F.2d 1232, 1235 (CCPA 1971) ("*Robert Moore* ") ("This first paragraph analysis in itself contains several inquiries. Considering the language of the statute, it should be evident that these inquiries include determining whether the subject matter defined in the claims is described in the specification, whether the specification disclosure as a whole is such as to enable one skilled in the art to make and use the claimed invention, and whether the best mode contemplated by the inventor of carrying out that invention is set forth."). The United States Supreme Court also recently acknowledged written description as a statutory requirement distinct not only from the best mode requirement, but also from enablement. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002) ("[A] number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103 (1994 ed. and Supp. V). In addition, the patent application must *describe, enable, and set forth the best mode* of carrying out the invention. § 112 (1994 ed.). These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public." (emphasis added)).

Although there is often significant overlap between the three requirements, they are nonetheless independent of each other. *In re Alton*, 76 F.3d 1168, 1172 (Fed.Cir.1996). Thus, an invention may be described without an enabling disclosure of how to make and use it. A description of a chemical compound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described. *See, e.g., In re DiLeone*, 58 C.C.P.A. 925, 436 F.2d 1404, 1405 (CCPA 1971) ("[I]t is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not describe that invention."). Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described. A specification *922 can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed.Cir.1987).

[4] The "written description" requirement serves a teaching function, as a "*quid pro quo* " in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." *Enzo*, 323 F.3d at 970. Rochester argues, however, that this teaching, or "public notice," function, [FN5] although "virtually unchanged since the 1793 Patent Act," in fact "became redundant with the advent of claims in 1870." We disagree. Statutory language does not become redundant unless repealed by Congress, in which case it no longer exists.

FN5. We and the Supreme Court have

> frequently used the term "public notice" in connection with claims and discussion of the doctrine of equivalents, the point being that the public is entitled to notice of what the inventor has claimed and the Patent and Trademark Office has agreed should be the subject of a patent's limited right to exclude. However, while the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement).

In addition, and most significantly, our precedent clearly recognizes a separate written description requirement. In *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990 (CCPA 1967), our predecessor court affirmed a rejection under 35 U.S.C. § 112 of a claim that was added to a patent application during prosecution to provoke an interference. That application had originally included a claim directed to a genus of chemical compounds, all having a central benzenesulphonylurea structure and two variable substituents attached at specified sites on that structure. *Id.* at 994. As a result of the way in which those substituents were defined in the claim, the genus defined by the claim included thousands of compounds, corresponding to all the possible permutations of the substituents. *Id.* at 993-94. The added claim, in contrast, was directed to a single member of that genus, N-(p-chlorobenzenesulfonyl)-N-propylurea. *Id.* at 991. Although that compound was within the literal scope of the originally filed claim, it was never "named or otherwise exemplified" in the appellants' original patent application. *Id.* at 992. The examiner rejected the added claim on the basis that the specific compound was not adequately supported by the specification as filed. *Id.*

The Patent Office Board of Appeals, and subsequently the Court of Customs and Patent Appeals, affirmed that rejection. In reaching its decision, the court observed that the claimed compound was not described in the specification and would not "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound." *Id.* at 996. It did not teach the specific compound. Although the appellants had argued that the rejection was improper because one skilled in the art would be enabled by the specification to make the specific compound, the court explained that it was "doubt[ful] that the rejection [was] truly based on section 112, at least on the parts relied on by appellants [*i.e.*, the 'language therein about enabling one skilled in the art to make the invention']. If based on section 112, it is on the requirement thereof that 'The specification shall contain a written description of the invention.' " *Id.* at 995-96.

[5] While it is true that this court and its predecessor have repeatedly held that *923 claimed subject matter "need not be described in haec verba" in the specification to satisfy the written description requirement, *e.g.*, *In re Smith*, 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." *Enzo*, 323 F.3d at 968. We have further explained that:

> [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement.... A description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [*Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.]*, 119 F.3d [1559,] 1568 [(Fed.Cir.1997) ("*Lilly* ")].... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Id.*

Enzo, 323 F.3d at 968. Similarly, for example, in the nineteenth century, use of the word "automobile" would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect.

Rochester is also factually incorrect in its assertion that a written description requirement separate from the enablement requirement was not recognized prior to *Ruschig* in 1967. For example, in *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533 (CCPA 1963), our predecessor court explicitly rejected the notion that an enabling disclosure necessarily satisfies the written description requirement: "It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily

discloses that particular device." *Id.* at 536. Still earlier, that court affirmed a decision of the Board of Appeals of the Patent Office affirming the rejection of an applicant's claims on the basis that those claims were "broader than the disclosure in appellant's application and ... were properly rejected for that reason." *In re Moore*, 33 C.C.P.A. 1083, 155 F.2d 379, 382 (CCPA 1946) ("*Wm. Moore* "). The court stated that it "is well settled that claims in an application which are broader than the applicant's disclosure are not allowable." *Id.*

Similarly, in 1962 the court affirmed the Board's rejection of the original claims in a patent application, based on, *inter alia*, the rejected claims' "fail[ure] to meet the requirements of 35 U.S.C. ß 112 in that they are broader than the invention described in the written description thereof as set forth in the specification." *In re Sus*, 49 C.C.P.A. 1301, 306 F.2d 494, 497 (CCPA 1962). In that case, the court specifically identified the "pertinent portions of 35 U.S.C. ß 112 to be here considered" as the following: " 'The specification shall contain a written description of the invention * * *. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.' " *Id.* at 494 n. 1 (ellipsis in original). According to the court, "one skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted *924 aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals would be suitable for such purposes." *Id.* at 504. [FN6] The issues in *Jepson*, *Wm. Moore*, and *Sus* were clearly not confined to a determination whether the enablement requirement was met. They were independent written description issues.

> FN6. In *Sus*, the claims at issue were rejected by the patent examiner under 35 U.S.C. ß 112, ð 2. However, the Court of Customs and Patent Appeals pointed out in subsequent cases that that rejection was "more properly considered under the first paragraph of that section." *In re Robins*, 57 C.C.P.A. 1321, 429 F.2d 452, 457 n. 8 (CCPA 1970).

Rochester's suggestion in its brief that *Lilly* "compounded *Ruschig* 's error" by "invoking the written description requirement in a case without priority issues" is similarly deficient. Neither *Wm. Moore* nor *Sus*, for example, involved any priority issues. Moreover, even if the court had never had occasion to apply the written description requirement to original claims prior to the 1987 *Lilly* decision, that requirement was nonetheless always present. As explained in *Enzo*:

> It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time....
> ... As for the lack of earlier cases on this issue, it regularly happens in adjudication that issues do not arise until counsel raise them, and, when that occurs, courts are then required to decide them.

323 F.3d at 971-72 (Lourie, J., concurring in Denial of Petition for Rehearing En Banc). In any event, the basic requirement of a written description of an invention exists whether a question of priority has arisen or not. The statute does not limit the requirement to cases in which a priority question arises.

Indeed, as early as 1822 the Supreme Court recognized the existence of separate written description and enablement requirements:

> [T]he patent act requires ... that the party [*i.e.*, the inventor] "shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before know[n], and to enable any person skilled in the art or science, & c. & c. to make, compound, and use the same." The specification, then has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent.... The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34, 5 L.Ed. 472 (1822). The Patent Act of 1793, 1 Stat. 318, which was in force at the time *Evans* was decided, required, in relevant part, that every inventor "deliver a written description of his invention, and of the manner of using, or process of compounding the

same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science ... to make, compound, and use *925 the same...." *In re Barker*, 559 F.2d 588, 592 (CCPA 1977) (ellipses in original). Although the patent statutes have been extensively revised since 1822, most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement. *Id.* at 592-94.

Rochester also argues that *Fiers v. Revel*, 984 F.2d 1164 (Fed.Cir.1993), *Lilly*, and *Enzo* are all distinguishable because they were limited to DNA-based inventions. Rochester asserts that undisputed evidence shows that, based on the '850 patent's teachings, skilled artisans would be able to recognize COX-2-selective inhibitors.

We agree with Rochester that *Fiers*, *Lilly*, and *Enzo* differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue; in fact, where there might be some basis for finding a written description requirement to be satisfied in a genetics case based on the complementariness of a nucleic acid and, for example, a protein, that correspondence might be less clear in a non-genetic situation. In *Enzo*, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." 323 F.3d at 964 (quoting from the PTO's *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1. "Written Description" Requirement*, 66 Fed.Reg. 1099, 1106). DNA and RNA are each made up of just four building blocks that interact with each other in a highly predictable manner. Each of those building blocks, or "nucleotides," is characterized by a unique "base": In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or "hybridizes," to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a "complementary" strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993-1995 period in which the applications that led to the '850 patent were filed. Rochester and its experts do not offer any persuasive evidence to the contrary. As the district court pointed out:

> Tellingly, ... what plaintiff's experts' [sic] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds--which, as the patent makes clear, are necessary to practice the claimed method--would be suitable, nor would one know how to find such a compound except through trial and error.... Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent *926 what method is claimed, but it is clear from reading the patent that one critical aspect of the method--a compound that selectively inhibits PGHS-2 activity--was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Univ. of Rochester, 249 F.Supp.2d at 229.

Rochester also attempts to distinguish *Fiers*, *Lilly*, and *Enzo* by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." *Univ. of Rochester*, 249 F.Supp.2d at 228. Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment." *Id.*

[6] We of course do not mean to suggest that the written description requirement can be satisfied only

by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless "describe the claimed subject matter in terms that establish that [the applicant] was in possession of the ... claimed invention, including all of the elements and limitations." *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed.Cir.1998). *But see Enzo*, 323 F.3d at 969 ("Application of the written description requirement, however, is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the *statutory* mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention."). The specification must teach the invention by describing it.

Rochester also contends that "[t]he patent-in-suit cannot be *per se* invalid," because written description is a question of fact. Rochester further argues that:

> [C]onsistent with written description's fact-intensive nature, this Court has recognized diverse forms of description, including description primarily (if not entirely) based on functional characteristics. In *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed.Cir.2000) ("*Unocal*")], for example, the Court rejected the argument that the patent-in-suit was invalid because it described claimed gasoline mixtures by their "desired characteristics," rather than by their "exact chemical component[s]."

In response, Pfizer argues that the district court did not apply a *per se* rule, and that written description of a method of selectively inhibiting the activity of an enzyme by administering a chemical compound is insufficient unless a skilled artisan can recognize the identity of the compound, and the description must convey what the compound is, not just what it does. Pfizer points out that the district court found that the '850 patent does not disclose the structure or physical properties of any of the compounds required to practice the claimed methods, and that the structure of such compounds cannot be deduced from any known structure-function correlation. Pfizer agrees with the district court that the '850 patent discloses nothing more than a hoped-for function for an as-yet-to-*927 be-discovered compound, and a research plan for trying to find it.

We agree with Pfizer that the '850 patent is deficient in failing to adequately describe the claimed invention. First, although compliance with the written description requirement is a question of fact, *Vas-Cath*, 935 F.2d at 1556, Rochester's argument that a patent may not be held invalid on its face is contrary to our case law. In *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235 (Fed.Cir.2002), for example, we held that a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met. Similarly, in *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111 (Fed.Cir.2001), we held that "[n]o reasonable juror could find that [an appellant's] original disclosure was sufficiently detailed to enable one of skill in the art to recognize that [the appellant] invented what is claimed," and accordingly upheld a grant of summary judgment. *Id.* at 1119.

Second, it is undisputed that the '850 patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known. The '850 patent does contain substantial description of the cyclooxygenases, including the nucleotide sequences of coding and promoter regions of the genes that encode human COX-1 and COX-2 and a comparison of those sequences. *See, e.g.*, '850 patent, figs. 6A-6B, 10A-10D, and 11A-11C. The patent also describes in detail how to make cells that express either COX-1 or COX-2, but not both, *id.* § 5.2, at cols. 8-20, as well as "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds," *id.* at col. 8, ll. 2-7; *see also id.* § 5.6, at cols. 24-25. Such assay methods are in fact claimed in the '479 patent, *i.e.*, Rochester's *other* patent based on the same disclosure. The '850 patent specification also describes what can be done with any compounds that may potentially be identified through those assays, including formulation into pharmaceuticals, routes of administration, estimation of effective dosage, and suitable dosage forms. *Id.* § 5.8, at cols. 27-34. As pointed out by the district court, however, the '850 patent does not disclose just "*which* 'peptides, polynucleotides, and small organic molecules' have the desired characteristic of selectively inhibiting PGHS-2." *Univ. of Rochester*,

249 F.Supp.2d at 224. Without such disclosure, the claimed methods cannot be said to have been described. As we held in *Lilly*, "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1171). For reasons stated above, that requirement applies just as well to non-DNA (or - RNA) chemical inventions.

Third, Rochester's reliance on *Unocal* is unavailing. Although we held in that case that a "descri[ption] of the exact chemical component of each combination that falls within the range claims of the ... patent" is not necessary to comply with § 112, we explained that the patentee is nonetheless required to provide sufficient description ***928** to show one of skill in the art that the inventor possessed the claimed invention at the time of filing. *Unocal*, 208 F.3d at 997. Evidence was adduced in that case that artisans skilled in petroleum refining were aware of the properties of raw petroleum sources and knew how to mix streams of such sources to achieve a final product with desired characteristics. Accordingly, we held that the written description requirement was satisfied in that case by specifying the ranges of properties of the claimed gasolines, reflecting the way that oil refiners actually formulate gasoline, such that one skilled in the art could recognize what was being claimed. *Id.* at 992. The present case is not analogous. Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description as "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product." [FN7]

> FN7. Indeed, if compounds that selectively inhibit activity of the PGHS-2 gene product *had* been known in the art, it is difficult to see how the claims of the '850 patent would have satisfied the novelty requirement of 35 U.S.C. § 102. After all, the novelty of those claims, if any, would appear to reside in the fact that COX-2 selective inhibitors were previously unknown. The issue of patentability under § 102, however, was not decided by the district court, and we do not address it further.

Rochester also cites *In re Edwards*, 568 F.2d 1349 (CCPA 1978), and *In re Herschler*, 591 F.2d 693 (CCPA 1979), in support of its arguments. Those cases are also inapposite. In *Edwards*, the court held that the written description requirement was satisfied by a specification that described a claimed compound by the process by which it was made, rather than by its structure, because the court found that Edwards' application, "taken as a whole, reasonably leads persons skilled in the art to the [recited reactions] and, concomitantly, to the claimed compound." 568 F.2d at 1354. In marked contrast to the Edwards application, the specification of the '850 patent contains no disclosure of any method for making even a single "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product." In *Herschler*, the court found adequate written description support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent and dimethyl sulfoxide ("DMSO"), even though the specification disclosed only one example of a "physiologically active steroidal agent." Critically, however, there was no question in that case that, unlike "non-steroidal compound[s] that selectively inhibit[ ] activity of the PGHS-2 gene product," numerous physiologically active steroidal agents were known to those of ordinary skill in the art. As the court there noted, "[w]ere this application drawn to novel 'steroidal agents,' a different question would be posed." 591 F.2d at 701. The novelty in that invention was the DMSO solvent, not the steroids.

Although cases such as *Unocal*, *Enzo*, *Edwards*, and *Herschler* demonstrate that patent applicants have some flexibility in the "mode selected for compliance" with the written description requirement, neither those cases nor any other cases cited by Rochester eliminate the requirement that the patent specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. The only claims that appear to be supported by the specification are claims to assay methods, but those claims were already issued in the '479 patent.

***929** Rochester argues that "[t]he appealed decision vitiates universities' ability to bring pioneering innovations to the public," and that:

> Congress has determined that licensing of academia's inventions to industry is the best way to bring groundbreaking inventions to the public. *See* 35 U.S.C. § 200. By vesting in universities the patent rights to their federally funded research, the

Bayh-Dole Act of 1980 encouraged "private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application." H.R.Rep. No. 96-1307, pt. 1, at 3 (1980).

Further, *amici* the University of California and the University of Texas assert that "[t]his Court's decision will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector."

That argument is unsound. The Bayh-Dole Act was intended to enable universities to profit from their federally-funded research. It was not intended to relax the statutory requirements for patentability. As pointed out by *amicus* Eli Lilly, "no connection exists between the Bayh-Dole Act and the legal standards that courts employ to assess patentability. Furthermore, none of the eight policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities. *See* 35 U.S.C. § 200." [FN8]

FN8. Section 200, entitled "Policy and objective," provides that:
It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.
35 U.S.C. § 200 (2000).

In sum, because the '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art [FN9] at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention. Accordingly, we affirm the district court's grant of Pfizer's motion for summary judgment.

FN9. In *O'Reilly v. Morse*, 56 U.S. 62, 15 How. 62, 14 L.Ed. 601 (1853), the Supreme Court stated "[Morse] claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law." *Id.* at 113. Likewise, Rochester has claimed a method that could not be adequately described at the time its application was filed. As we explained in *Fiers*, "one cannot describe what one has not conceived." 984 F.2d at 1171.

In view of our affirmance of the district court's decision on the written description *930 ground, we consider the enablement issue to be moot and will not discuss it further.

With respect to the third asserted error, relating to the denial of Rochester's cross-motion for summary judgment, Rochester argues that because Pfizer adduced no evidence, other than the patent in suit, to support its written description defense, Rochester was entitled to summary judgment on that issue. Rochester contends that, because all issued patents are presumed to be valid, the district court was wrong to conclude that the '850 patent constitutes clear and convincing proof of its own invalidity.

Pfizer responds by arguing that there is no issue of material fact in dispute and that the '850 patent is invalid as a matter of law. Pfizer argues further that the district court properly found that Rochester's experts' declarations did not raise any issue of material fact, because they focused only on the use

and function of the screening assay, rather than on the disclosure in the specification of a suitable compound. According to Pfizer, common sense dictates that one has not described a method of treating a disease with a drug if he has not disclosed any such drug or even if one exists, and there is accordingly no need for any evidence of invalidity beyond the '850 patent itself.

[7] Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity, *see, e.g., PIN/NIP*, 304 F.3d at 1235; *TurboCare*, 264 F.3d at 1111, and as detailed in section I above, we conclude that the '850 patent clearly and convincingly does just that. The patent's claims all require a COX-2 selective compound, but no COX-2 selective compound is disclosed in the patent, and it is undisputed that there was no pre-existing awareness in the art of any compound having COX-2 selective activity. Accordingly, we hold that the district court did not abuse its discretion by denying Rochester's cross-motion for summary judgment. [FN10]

FN10. Although we have treated the issue in this case as one of written description, as it was argued and decided below, underlying that question is the fundamental issue whether Rochester actually invented the subject matter it claimed in the '850 patent as required by 35 U.S.C. § 102(f). As the Supreme Court has cautioned, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966). Here the patentee has done no more than invent a search method, *i.e.*, a method of identifying a selective COX-2 inhibitor, much less did it invent, as claimed in the '850 patent, a method of using any such compound to selectively inhibit COX-2 in humans. Under these circumstances, it might appear that the patentee also failed to satisfy the requirements of section 102(f).

CONCLUSION

Because the court did not err in holding the '850 patent to be invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment in favor of Pfizer on that ground, the decision of the district court is

AFFIRMED.

358 F.3d 916, 185 Ed. Law Rep. 122, 69 U.S.P.Q.2d 1886

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